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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,827	12/24/2003	Paul William Martens	2625-114	1144
6449	7590 09/01/2006		EXAM	INER
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W.			HUH, BENJAMIN	
SUITE 800		ART UNIT	PAPER NUMBER	
WASHINGTON, DC 20005			3767	

DATE MAILED: 09/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
Office Action Summary	10/743,827	MARTENS ET AL.			
omee meen cummary	Examiner	Art Unit			
The MAILING DATE of this communication and	Benjamin Huh	orrespondence address			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1) Responsive to communication(s) filed on <u>5/10/04</u> .					
,	, <del></del>				
·	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4) Claim(s) 1-7 & 9-25 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) 1-7 & 9-25 is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) are subject to restriction and/or election requirement.					
Application Papers					
<ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>					
Priority under 35 U.S.C. § 119	,				
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)		,			
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5/10/04</u>.</li> </ol>	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:				

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#### **DETAILED ACTION**

### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the step of actually infusing the fluid into a patient is omitted from the claim as well as providing the actual fluid warming and infusion system of claim 1. Appropriate correction is required.

## Claim Objections

Claim 8 is objected to because of the following informalities: Claim 8 is missing from the claims. Appropriate correction is required.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 & 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Maruschak (US Patent No. 5601894). The Maruschak reference discloses the device

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and use of a fluid warming and infusion system for infusing a warm fluid into a patient comprising a device that transfers heat to the fluid, see col. 1 lines 38-61 & col. 6 line 61 – col. 7 line 47, thereby warming the fluid and an insulated tube seen in figures 1A-C that transports the warmed fluid to the patient wherein the insulated tube includes a substantially thermally insulating component that prevents the warmed fluid from losing a substantial amount of heat as the fluid flows through the tube.

Claims 1 & 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Swenson (US Patent No. 5195976). The Swenson reference discloses the device and use of a fluid warming and infusion system for infusing a warm fluid into a patient comprising a device 41 that transfers heat to the fluid, thereby warming the fluid and an insulated tube 32 that transports the warmed fluid to the patient wherein the insulated tube includes a substantially thermally insulating component 47 that prevents the warmed fluid from losing a substantial amount of heat as the fluid flows through the tube, also see figure 3 and col. 6 lines 24-48.

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 1-2, 4, 7, 9-13, 15, 18-20, 22, & 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ford et al (US Patent No. 5381510) and further in view of Verkaart (US Patent No. 5063994). The Ford reference discloses the use of a fluid warming and infusion system for infusing a warm fluid into a patient in figure 1 comprising a heat exchanger cassette that transfers heat to the fluid, thereby warming the fluid and a fluid line. Now even though the Ford reference does not explicitly disclose an insulated tube attention is directed to Verkaart. The Verkaart reference teaches the use of an insulated tube/patient line in figures 3-6 that transports the warmed fluid to the patient wherein the insulated tube includes a substantially thermally insulating component, seen as the heat exchange fluid, that prevents the warmed fluid from losing a substantial amount of heat as the fluid flows through the tube, see col. 2 line 56 - col. 3 line 46.. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to utilize the teachings of Verkaart with the device of Ford in order to provide a warmed fluid to the patient without substantial heat loss over the course of infusion and to allow a fluid of a desired temperature to be delivered even over a low flow rate to the patient.

With respect to claims 2, 7, 13, 18, 20, & 25, wherein the insulated tube has a configuration consisting of an outer wall, an inner wall that forms a fluid lumen for transporting the warmed fluid, and at least two partitions connected between the inner and outer walls for forming at least two insulating gaps between the inner and outer walls and wherein the partitions are spaced about 180 degrees apart from each other, see Verkaart figure 4.

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With respect to claims 4, 15, & 22, wherein each insulating gap is filled with an insulating material, wherein the heat exchange fluid is seen to be an insulating material.

With respect to claim 11, further comprising a luer connector 32 attached to a distal end of said insulated tube, see Verkaart figure 3 and col. 3 lines 13-28.

Claims 3, 5-6, 14, 16-17, 21, & 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ford et al (US Patent No. 5381510) in view of Verkaart (US Patent No. 5063994) as applied to claim 1 and further in view of Dobak, III (US Patent No. 6042559). Now even though Ford in view of Verkaart does not explicitly disclose the use of a vacuum or insulating foam in the insulated tube attention is directed to Dobak, III. The Dobak, III reference teaches the use of an insulated tube with a vacuum wherein the insulating material is comprised primarily of air or an insulated tube wherein the insulating material comprises insulating foam, see figure 4 and col. 4 lines 62-65, col. 5 line 52-col. 6 line 29. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to utilize the teachings of Dobak III with the device of Ford in order to provide a tube that is compact and well insulated.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KEVIN C. SIRMONS SUPERVISORY PATENT EXAMINER

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